DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
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September 23, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warning Letter
(CIN-WL-02-13061-0)

Monte R. Black, President/CEO
MPW Industrial Services, Inc.
9711 Lancaster Road S.E.
Hebron, Ohio 43025

Dear Mr. Black:

On April 17, 19, 22, and 23, and May 8, 2002, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 2848 Interstate Parkway, Brunswick, Ohio. During the FDA inspection, our Investigator collected information that revealed serious regulatory problems involving the MPW Hemodialysis Water Purification System and regenerated mixed bed DI tanks which are manufactured and distributed by your firm. Under the Federal Food, Drug, and Cosmetic Act (the Act), your firm's MPW Hemodialysis Water Purification System is considered to be a medical device and the regenerated mixed bed deionization (DI) tanks for medical purposes are components used in hemodialysis water purification systems. The law requires that manufacturers of medical devices conform to the requirements of the Quality System Regulation (QS Regulation) as specified in Title 21, Code of Federal Regulations (C.F.R.), Part 820.

Your firm's devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for their manufacture, packing, storage, or installation are not in conformance with the requirements of the QS Regulation. The inspection revealed the following deviations from the QS Regulation:

1. Failure of management with executive responsibility to ensure that a quality policy has been fully implemented and maintained at all levels of your organization. 21 C.F.R. § 820.20(a). No quality plan, setting forth the quality practice, resources, and activities relevant to the devices your firm designs and manufactures, has been established. There are no management review procedures and management reviews are not conducted.

2. Failure to establish procedures for quality audits and conduct such audits to assure that your firm's quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. 21 C.F.R. § 820.22. No quality audits have been conducted.

3. Failure to establish written procedures to control the design of the medical devices your firm manufactures in order to ensure that specified design requirements are met. 21 C.F.R. § 820.30(a). There are no written procedures controlling the design of your firm's DI tanks which are regenerated using your firm's Manual Mixed Bed Regeneration System. Also, there are no procedures controlling the design of your firm's Water Purification System for Hemodialysis. No design history files for these devices have been established and maintained as required by 21 C.F.R. § 820.30(j).

4. Failure to establish and maintain procedures for implementing corrective and preventative action. 21 C.F.R. § 820.100. There are no analyses performed of processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product and other sources of quality data to identify existing and potential causes of nonconforming or other quality problems. There are no controls in place to prevent the distribution of nonconforming product.

5. Failure to validate processes where the results of the processes cannot be fully verified by subsequent inspection and test. 21 C.F.R. § 820.75(a). For example, the regeneration process for DI tanks using your firm's Manual Mixed Bed Regeneration System and your firm's manufacturing process for the MPW Water Purification System for Hemodialysis have not been validated.

6. Failure to establish and maintain written procedures for the receiving, reviewing, and evaluation and when appropriate, investigation of complaints by a formally designated unit to ensure that all complaints are processed in a uniform and timely manner. 21 C.F.R. § 820.198(a). Also, complaints are not reviewed and evaluated to determine whether they represent an event reportable to the FDA under 21 C.F.R. Part 803, Medical Device Reporting. 21 C.F.R. §§ 820.198(c) & (d).

7. Failure to establish and maintain process control procedures that describe process controls necessary to ensure conformance to specifications. 21 C.F.R. § 820.70(a). For example, no microbiological or endotoxin testing is performed to ensure that regenerated DI tanks are not contaminated with microorganisms or endotoxin. Equipment such as the resistivity monitor, hydrometers, thermometers and pressure gauges is not calibrated. Your firm uses this equipment to assure that the process of regenerating the DI tanks is consistent and maintained within tolerances.

In addition, your firm's medical devices are misbranded under Section 502(t) (2) of the Act (21 U.S.C. § 352(t)). Specifically, your firm failed to develop and maintain written Medical Device Reporting (MDR) procedures as specified in 21 C.F.R. § 803.17.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for export certificates will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We received your firm's letter of response to the Form FDA 483 that was issued to management at the close of the FDA inspection of your firm on May 8, 2002. The letter promised corrective action with regard to your firm's compliance with the Quality System Regulation. The letter did not include any documentation of any specific actions your firm has taken to correct the deficiencies that were pointed out to management at your firm.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Road, Cincinnati, Ohio 45237.

Sincerely,

John W. Thorsky
Acting District Director
Cincinnati District

Cc: William T. Watson,
Senior Sales Representative & FDA Correspondent
MPW Industrial Services, Inc.
2848 Interstate Parkway
Brunswick, OH 44212